



**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Disease Control and Prevention**

**[60Day-23-0109; Docket No. CDC-2022-0135]**

**Proposed Data Collection Submitted for Public Comment and Recommendations**

**AGENCY:** Centers for Disease Control and Prevention (CDC),  
Department of Health and Human Services (HHS).

**ACTION:** Notice with comment period.

**SUMMARY:** The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other federal agencies the opportunity to comment on a continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled Respiratory Protective Devices—42 CFR part 84—Regulation. The purpose of the data collection is to enable 42 CFR part 84 respirator approval certification activities.

**DATES:** CDC must receive written comments on or before **[INSERT DATE 60 DAYS AFTER PUBLICATION DATE IN THE FEDERAL REGISTER]**.

**ADDRESSES:** You may submit comments, identified by Docket No. CDC-2022-0135 by either of the following methods:

- Federal eRulemaking Portal: [www.regulations.gov](https://www.regulations.gov). Follow the instructions for submitting comments.

- Mail: Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, NE, MS H21-8, Atlanta, Georgia 30329.

**Instructions:** All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to [www.regulations.gov](http://www.regulations.gov).

Please note: Submit all comments through the Federal eRulemaking portal ([www.regulations.gov](http://www.regulations.gov)) or by U.S. mail to the address listed above.

**FOR FURTHER INFORMATION CONTACT:** To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, NE, MS H21-8, Atlanta, Georgia 30329; Telephone: 404-639-7570; E-mail: [omb@cdc.gov](mailto:omb@cdc.gov).

**SUPPLEMENTARY INFORMATION:** Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires federal agencies to provide a 60-day notice in the *Federal Register* concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the

OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
3. Enhance the quality, utility, and clarity of the information to be collected;
4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses; and
5. Assess information collection costs.

#### Proposed Project

Respiratory Protective Devices – 42 CFR part 84 (OMB Control No. 0920- 0109, Exp. 03/31/2024) – Revision – National Institute for

Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC).

### Background and Brief Description

The regulatory authority for the National Institute for Occupational Safety and Health (NIOSH) certification program for respiratory protective devices is found in the Mine Safety and Health Amendments Act of 1977 (30 U.S.C. 577a, 651 et seq., and 657(g)) and the Occupational Safety and Health Act of 1970 (30 U.S.C. 3, 5, 7, 811, 842(h), 844). These regulations have, as their basis, the performance tests and criteria for approval of respirators used by millions of American construction workers, miners, painters, asbestos removal workers, fabric mill workers, and fire fighters.

Regulations of the Environmental Protection Agency (EPA) and the Nuclear Regulatory Commission (NRC) also require the use of NIOSH-approved respirators. These regulations also establish methods for respirator manufacturers to submit respirators for testing under the regulation and have them certified as NIOSH-approved if they meet the criteria given in the above regulation. This data collection was formerly named Respiratory Protective Devices 30 CFR part 11 but in 1995, the respirator standard was moved to 42 CFR part 84.

NIOSH, in accordance with 42 CFR part 84: (1) issues certificates of approval for respirators which have met specified construction, performance, and protection

requirements; (2) establishes procedures and requirements to be met in filing applications for approval; (3) specifies minimum requirements and methods to be employed by NIOSH and by applicants in conducting inspections, examinations, and tests to determine effectiveness of respirators; (4) establishes a schedule of fees to be charged for testing and certification; and (5) establishes approval labeling requirements. Information is collected from those who request services under 42 CFR Part 84 in order to properly establish the scope and intent of request.

Information collected from requests for respirator approval functions includes contact information and information about factors likely to affect respirator performance and use. Such information includes, but is not necessarily limited to, respirator design, manufacturing methods and materials, quality assurance plans and procedures, and user instruction and draft labels, as specified in the regulation.

The main instrument for data collection for respirator approval functions is the Standard Application Form for the Approval of Respirators (SAF), currently Version 9. Respirator manufacturers are the respondents (estimated to average 140 each year over the years 2020-2023) and upon completion of the SAF their requests for approval are evaluated. A total of 375 applications were submitted in CY2019. To date, 300 applications have been submitted in CY2020. The increased submission rate is due to the publication of a new respirator class, PAPR100, as

well as increased certification requests due to COVID-19. The applications are submitted, at will, and taking into account both historical conditions as well as the current situation, our prediction of the number of respondents each year between CY2020 and CY2022 is 140. A \$200 fee is required for each application. Respondents requesting respirator approval or certain extensions of approval are required to submit additional fees for necessary testing and evaluation as specified in 42 CFR parts 84.20-22, 84.66, 84.258 and 84.1102.

Applicants are required to provide test data that shows that the manufacturer is able to ensure that the respirator is capable of meeting the specified requirements in 42 CFR part 84. The requirement for submitted test data is likely to be satisfied by standard testing performed by the manufacturer, and is not required to follow the relevant NIOSH Standard Test Procedures. As additional testing is not required, providing proof that an adequate test has been performed is limited to providing existing paperwork.

The secondary instruments for data collection for respirator approval functions are instruments used to collect data from human subjects who are serving as test fixture surrogates to perform tests while wearing the respirator being evaluated. Such instruments are completed by the human subject or test operator and are limited to specific information required for the test.

Approvals under 42 CFR part 84 offer corroboration that approved respirators are produced to certain quality standards. Although 42 CFR part 84 Subpart E prescribes certain quality standards, it is not expected that requiring approved quality standards will impose an additional cost burden over similarly effective quality standards that are not approved under 42 CFR part 84.

Manufacturers with current approvals are subject to site audits by the Institute or its agents. Audits may occur periodically (typically every second year), or because of a reported issue. Approximately, 50% of the sites are audited each year, each having a primary point of contact. It is estimated that the average number of site audits over the next three years will be 89.

CDC requests OMB approval for an additional three years of data collection. The estimated annual burden hours are 130,689.

Estimated Annualized Burden Hours

Type of Respondents	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Total Burden (in hours)
Business or other for-profit	Standard Application Form for the Approval of Respirators	140	4	229	128,240
Business or other for-profit	Audit	89	1	16	1424
	Human Participant - Consent	425	1	12/60	85

Member of general public	Human Participant - Subject payment information	425	1	24/60	170
	Human Participant - Questionnai re	425	1	12/60	85
	Human Participant - Information Sheet	425	1	12/60	85
	Human Participant - Data Collection Form	150	1	4	600
Total					130,689

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